REMARKS

Claims 1-31 are pending in this case. Claims 1-14 stand rejected in a Final Office Action mailed October 12, 2007. Claims 15-31 have been withdrawn from consideration in view of a restriction requirement.

Applicants are presenting herein a Request for Continued Examination, canceling claims 2-4, 6, 7, 11, 13 and 14, amending claims 1, 5 and 9 and adding new independent claims 32 and 36 and dependent claims 33-35 and 37. In view of the claim amendments and Applicants remarks, Applicants respectfully request the Examiner's consideration and allowance of claims 1,5,8,9,10, 12, and 32-37.

Applicants thank the Examiner for withdrawing the rejections of claim 1 under 35 U.S.C. §112 2nd paragraph, claims 1-5, 7-10 and 13 under 35 U.S.C. §102(b) over Wehling, and claims 1-14 under 35 U.S.C. §103(a) over Korab in view of Mauger in the Office Action of October 12, 2007.

Amended Claims

Amended independent claim 1 is presented for the Examiner's consideration. The amendment of claim 1 removes the phrase "non-effervescent" from the preamble. Further, Applicants have replaced the phrase "water soluble excipient" with saccharide and added the limitation "and wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet". This amendment is supported, for example, by Example 8 and paragraph 29 of the specification. As claims 8-10 and 12 variously depend from claim 1, the amendment likewise applies to dependent claims 8-10 and 12 that depend from claim 1.

Applicants have amended claim 5 to specifically claim mannitol, and claim 9 to specifically claim hydrogenated or partially hydrogenated oil – elements within the scope of original claims 5 and 9.

Applicants believe that these amended claims further point out and distinguish Applicants' invention. Applicants respectfully request that the Examiner consider these proposed amendments and allow amended independent claim 1 and dependent claims 5, 8-10, 12 which variously depend from claim 1.

New Claims

Applicants have added new independent claim 32 directed to a tablet comprising a fast dissolving granulation, and an active ingredient where in the fast

dissolving granulation consists essentially of a saccharide and low melting point compound that melts or softens at or below 37°C and wherein the low melting point compound comprises less than about 20% (wt/wt) of the fast dissolving granulation and from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of less than about 2 kP. Support for this claim is found in Example 8 of the specification and paragraph 23 of the specification, for example.

New dependent claims 33-35 depend from claim 32 and parallel original claims 5, 9, and 10, respectively.

Applicants have added new independent claim 36 directed to a tablet comprising a fast dissolving granulation, and an active ingredient wherein the fast dissolving granulation consists essentially of a saccharide and low melting point compound that melts or softens at or below 37°C selected from the group consisting of hydrogenated vegetable oil, and partially hydrogenated vegetable oil. and wherein the low melting point compound comprises less than about 20% (wt/wt) of the fast dissolving granulation and from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of less than about 2 kP. Support for this claim is found in Example 8 of the specification and paragraph 23 of the specification, for example.

New dependent claim 37 depends from claim 36 and parallels original claim 5.

Applicants believe that these new claims further point out and distinguish Applicants' invention. Accordingly, Applicants respectfully request that the Examiner enter and allow new claims 32-37.

Rejection Under 35 USC §112

The Examiner has rejected claim 1 under 35 U.S.C. § 112, first paragraph for the addition of the phrase "non-effervescent tablet". The phrase to which the Examiner has objected has been removed by the present amendment. Accordingly, the Examiner's rejection of Claim 1 under 35 U.S.C. § 112 is rendered moot by the current amendment.

Applicants' respectfully request that the rejection of claim 1 under 35 USC §112, first paragraph be withdrawn.

Rejection Under 35 USC §102 - Mizumoto

Claims 1, 4, 5, 7-9 and 14 stand rejected as anticipated by Mizumoto et al. (U.S. 5,576,014, herein "Mizumoto"). The rejection is rendered moot as to claims 4, 7 and 14 which have been cancelled with the current amendment. The composition of Mizumoto is an intrabuccally dissolving compressed molding. Mizumoto teaches a composition that achieves the desired dissolution properties by combining low moldability and high moldability saccharides (see col. 5., lines 60-67 and Claim 1). In the Office Action of October 12, 2007, the Examiner cites Mizumoto for disclosing a list of saccharides, the inclusion of an active, a list of lubricants and a general listing of excipients.

Nowhere does Mizumoto disclose or suggest a fast dissolving granulation and/or the combination of a saccharide and low melting point compound to form a fast dissolving granulation wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet as currently amended independent claim 1 sets forth. The standard of anticipation is whether a person of skill in the art would understand or infer that every claim element is disclosed in the prior reference. *Dayco Prods. Inc. v. Total Containment Inc.* 329 F.3d 1358 138-69 (Fed. Cir. 2003). Mizumoto teaches that the desired buccal dissolving properties are derived from a combination of low and high moldability saccharides not a fast dissolving granulation comprising a low melting point compound and a saccharide. Further, the listings of saccarides, lubricants and other excipients of Mizumoto are just that - listings. Nowhere do they teach or suggest a fast dissolving granulation of a low melting point compound and a saccharide and/or that such a granulation should comprise about 30% to about 70% of the tablet by weight and or that the amount of low melting point compound should be about 0.01% to about 2.5% (wt/wt) of the tablet. Accordingly, Mizumoto does not set forth or infer every claim element of Applicants' claim 1.

As claims 5, 8 and 9 variously depend from claim 1, the present amendment to claim 1 replacing the term "low melting point compound" with "saccharide" and adding the limitation "and wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet", applies to claims 5, 8 and 9. Accordingly, the amendment also further distinguishes claims 5, 8 and 9 from Mizumoto for the reasons discussed above.

In view of at least these distinctions and the fact that Applicants have amended independent Claim 1 to further specify a saccharide as a component of the

fast dissolving granulation and that the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet, Applicants respectfully request that the Examiner withdraw the rejection of claims 1,5, 8 and 9 as anticipated under 35 USC §102 (b) by Mizumoto et al.

Rejection Under 35 USC §102 (e) - Shimizu

Claims 1,4,5, 7-9 and 14 stand rejected as anticipated by Shimizu et al. (U.S. 6,299,904 B1, herein "Shimizu"). The rejection is rendered moot as to claims 4, 7 and 14 which have been cancelled with the current amendment. As the Examiner states, Shimizu teaches a composition comprising a pharmaceutically active ingredient, one or more sugar alcohols selected *from the group consisting of* sorbitol, maltitol, reduced starch saccharide, xylitol, reduced papatinose and erythritol, and a hydroxproypyl cellulose.

Nowhere does Shimziu disclose or suggest a fast dissolving granulation and/or the combination of a saccharide and low melting point compound to form a fast dissolving granulation wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet as currently amended independent claim 1 sets forth. The standard of anticipation is whether a person of skill in the art would understand or infer that every claim element is disclosed in the prior reference. *Dayco Prods. Inc. v. Total Containment Inc.* 329 F.3d 1358 138-69 (Fed. Cir. 2003). Shimizu teaches a combination of one or more of a limited number of sugar alcohols with a very hydroscopic material hydroxypropylcellulose. No where does Shimizu teach or suggest a fast dissolving granulation to achieve a fast dissolving tablet and/or a fast dissolving granulation made up of a low melting point compound and a saccharide and/or that such a granulation should comprise about 30% to about 70% of the tablet by weight and/or that the amount of low melting point compound should be about 0.01% to about 2.5% (wt/wt) of the tablet. Accordingly, Shimizu does not set forth or infer every claim element of Applicants' claim 1.

As claims 5, 8 and 9 variously depend from claim 1, the present amendment to claim 1 replacing "low melting point compound" with "saccharide" and adding the limitation "and wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet", applies to claims 5, 8 and 9. Accordingly, the amendment also further distinguishes claims 5, 8 and 9 from Shimizu for the reasons discussed above.

The Examiner has cited Col. 8, lines 5-8 of Shimizu for a tablet of hardness of about 2 to about 20 kg. Applicants claim a tablet of less than about 2 kP. Applicants' claim is supported, for example, in Example 8 which recites that for compositions 1 and 2 of Example 8, the hardness ranges were 0.45 – 1.4 kP, 0.7 – 1.7 kP, respectively. Thus, the hardness range claimed by Applicants is consistent with the hardness measured for exemplary embodiments of Applicants' composition and a range that is lower than the range of 2-20 kg of Shimizu cited by the Examiner or the preferred hardness range of Shimizu which is about 4 to about 15 kg . (See Shimizu Col. 8, line 5-9.) One skilled in the art recognizes that tablet hardness may impact a number of properties of a tablet including for example, processability, robustness and dissolution behavior. As the data presented in Example 8 shows, Applicant's composition is tabletable to form a tablet with substantially lower hardness that that of Shimizu. Namely, in contrast to Shimizu whose tablet hardness if in the range of 2-20 kg and preferably 4-15 kg, Applicants' composition forms a satisfactory tablet with a hardness less than 2 kP.

As claims 5, 8 and 9 variously depend from claim 1, the present amendment to claim 1 replacing the term "low melting point compound" with "saccharide" and adding the limitation "and wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet", applies to claims 5, 8 and 9. Accordingly, the amendment also further distinguishes claims 5, 8 and 9 from Shimizu for the reasons discussed above.

In view of at least these distinctions and the fact that Applicants have amended independent Claim 1 to further specify a saccharide and that the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet", Applicants respectfully request that the Examiner withdraw the rejection of claims 1,5, 8 and 9 as anticipated under 35 USC §102 (b) by Shimizu et al.

Rejection Under 35 USC §103 – Wehling in View of Mauger

Claims 1-14 stand rejected under 35 USC §103 over Wehling et al. (US 5,178,878) in view of Mauger et al. (US 5,728,403, herein "Mauger"). The rejection is rendered moot as to claims 2-4, 6, 7, 11, 13 and 14 which have been cancelled with the current amendment.

Wehling is directed to a pharmaceutical dosage form that comprises microparticles combined in a tablet with an effervescent disintegration agent (see

abstract of Wehling), and teaches both that an effervescent agent is necessary for rapid disintegration of the tablet and that the effervescent agent is the component responsible for the rapid disintegration of the tablet. Nowhere does Wehling disclose or suggest a fast dissolving granulation to achieve rapid dissolution of a tablet and/or a the combination of a saccharide and low melting point compound to form a fast dissolving granulation wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet as currently amended independent claim 1 sets forth.

Further there is no motivation in Wehling to use a fast dissolving granulation of a saccharide and low melting point compound to achieve a fast dissolving tablet. Wehling teaches the use of effervescent disintegration agents to cause a tablet to disintegrate and release coated microparticles See column 2, lines 18-51. Disintegration is a different process than dissolving; e.g. disintegration is the process of breaking up while dissolving is to cause a substance to pass into solution. See Dorlands Medical Dictionary on line at www.mercksource.com.

Further, Wehling's general list of optional lubricants cited by the Examiner includes high melting point solids such as sodium benzoate - m.p.300°C and magnesium oxide – m.p.2800°C) which have melting points substantially above the 37°C of the low melting compounds of Applicant's invention. (See specification paragraph 24) Thus, Wehling provides no motivation or guidance that a low melting point compound should be used or any reason to believe that a low melting point compound would impart desirable properties to a fast dissolving granulation.

Thus, Wehling neither teaches or suggests a fast dissolving granulation and/or a granulation of a saccharide and a low melting point compound; and/or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation. Accordingly, Wehling neither teaches or suggests a fast dissolving tablet formed form a fast dissolving granulation that comprises about 30% to about 75% of the weight of the tablet or that the low melting point compound should comprise from about 0.01% to about 2.5% of the tablet. Wehling also does not provide a reasonable expectation of success because Wehling teaches a fast dissolving tablet based on a gas forming chemical reaction and does not suggest other alternatives.

The deficiencies of Wehling are not cured by Mauger. Mauger is directed to a taste masking coating not to a tablet that dissolves readily (see abstract, column 1,

lines 56-65 and claim 1). Arguably, Mauger doesn't even teach a fast dissolve coating much less a fast dissolve tablet. The coating of Mauger is a mixture of triglycerides and a polymer with the coating intended to remain intact until the tablet reaches the stomach (col. 2 lines 21-29). As the coating of Mauger is designed to remain intact until the tablet reaches the stomach, dissolution of the tablet would be delayed until the tablet reached the stomach and the coating had been breached – this process is inconsistent with a fast dissolve dosage form. As the Examiner notes (citing Mauger, col.2, lines 39-63) on page 7 lines 13 and 14, the coating of Mauger "melts". Melting means undergoing or causing to undergo the transition from solid to liquid [e.g. a phase change], while dissolving is to cause a substance to pass into solution. See Dorlands Medical Dictionary on line at www.mercksource.com. Thus, the attribute of the coating of Mauger is to undergo a physical phase change in the warmth of the body as opposed to dissolving.

Herein Applicants' have amended claim 1 to specifically claim a saccharide as an element of the fast dissolving granulation. Mauger provides no teaching, suggestion, or motivation to use a saccharide even in the coating disclosed in Mauger much less any other capacity. Further, Mauger provides no teaching disclosure or motivation to use a fast dissolving granulation in a tablet in any capacity coating or otherwise. Accordingly, Mauger does not disclose, suggest or provide motivation for combining saccharide with a low melting point solid form to a fast dissolving granulation, and no teaching, suggestion or motivation for forming a tablet wherein about 30% to about 75% of the weight of the tablet is a fast dissolving granulation of a saccharide and a low melting point solid.

Mauger neither teaches or suggests the elements needed to cure the identified deficiency of Wehling - namely Mauger does not teach or suggest that a saccharide and a low melting point compound are required; and/or or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation and/or that the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet.

Thus, there is no teaching or suggestion in Wehling, Mauger or in the combination of Wehling and Mauger of Applicants' invention of a fast dissolve granulation and/or of combining of a saccharide and low melting point compound to form a fast dissolving granulation for use in a fast dissolve tablet. Accordingly, there is no teaching or suggestion that the fast dissolving granulation should be used in an

amount of about 30% to about 75% of the weight of the tablet to form a fast dissolving tablet. Further, the combination of Wehling and Mauger do not provide any reason or guidance for modifying an effervescent tablet and a coating that melts in the stomach to form a fast dissolving granulation. The Court of Appeals for the Federal Circuit recently held that in cases involving new chemical compounds, "it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Takeda Chemical Industries, Ltd. v. Alphapharm Pyt, Ltd.*, No. 06-1329 (Fed. Cir. June 28, 2007), page 10.

As claims 5, 8, 9, 10 and 12 variously depend from claim 1, the present amendment to claim 1 replacing the term "low melting point compound" with "saccharide" and adding the limitation "and wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet", applies to claims 5, 8, 9, 10 and 12, the amendment also further distinguishes claims 5, 8, 9, 10 and 12 from Wehling and Mauger for the reasons discussed above.

In view of at least these distinctions and the fact that Applicants have amended independent Claim 1 to replace " water soluble excipient" with at least one saccharide and specify that the fast dissolving granulation "comprises about 30% to about 75% of the weight of the tablet", Applicants respectfully request that the Examiner withdraw the rejection of claims 1,5, 8-10, and 12 under 35 USC §103 over Wehling et al. (US 5,178,878) in view of Mauger et al. (US 5,728,403).

Rejection Under 35 USC §103 – Mizumoto in view of Mauger

Claims 1-14 stand rejected under 35 USC §103 over Mizumoto et al. (US 5,576,014) in view of Mauger et al. (US 5,728,403 , herein "Mauger"). The rejection is rendered moot as to claims 2-4, 6, 7, 11, 13 and 14 which have been cancelled with the current amendment.

As discussed in detail above, Mizumoto teaches a composition that achieves the desired dissolution properties by combining low moldability and high moldability saccharides (see col. 5., lines 60-67 and Claim 1). Mizumoto clearly sets forth that the desirable features of the Mizomoto composition are derived from combining at least one of a "high moldability saccharide" and at least one of a "low moldability saccharide" (Col. 5 lines 12-67). No where does Mizumoto teach or suggest a fast dissolving granulation of a saccharide and a low melting point compound.

In contract to Applicants' invention, Mizumoto neither teaches or suggests that *a* saccharide is required (Mizumoto requires at least two saccharides with specified moldabilities). Mizumoto stresses the importance of having both a low and high moldability saccharides present and teaches that that they should be granulated together to get the best characteristics of each (col. 5, lines 52-66). Further Mizumoto neither teaches or suggests that a saccharide and a low melting point compound form a fast dissolving granulation; and/or or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation and/or that the fast dissolving granulation comprises about 30% to about 75% of the weight of the fast dissolve tablet as Applicants' currently amended claim requires.

Mizumoto provides no suggestion or motivation to substitute a low modability saccharide or a high moldability saccharide with a low melting point compound to create a fast dissolving tablet.

As discussed above, the listing of lubricants in Mizumoto is a general listing of optional lubricants - including lubricants such as magnesium stearate, talc and stearic acid have melting points substantially above 37°C. See column 13, lines 50-65. No distinction is made in Mizumoto as to any merit in using a low melting point compound and/ or there is no teaching or suggestion in Mizomoto of combining a low melting point compound that melts below 37°C with a saccharide to form a fast dissolving granulation.

Mizumoto also does not provide a reasonable expectation of success combining a low melting point compound with a saccharide to form a fast dissolving granulation and/or or any guidance as to the amount of such a granulation that would need to be used in a tablet to form a fast dissolve tablet. Mizumoto focuses on achieving a compression molded formulation showing quick disintegration and fast dissolution by inclusion of granules comprising at least two sacchardes – one with low moldability properties and one with high moldability properties and provides no motivation for using a fast dissolving granulation comprising a saccharide and a low melting point compound.

The deficiencies of Mizumoto are not cured by Mauger. Mauger is directed to a taste masking coating not to a tablet that dissolves readily (see abstract, column 1, lines 56-65 and claim 1). Arguably, Mauger doesn't even teach a fast dissolve coating much less a fast dissolve tablet. The coating of Mauger is a mixture of triglycerides and a polymer with the coating intended to remain intact until the tablet

reaches the stomach. (See col. 2 lines 21-29.) As the coating of Mauger is designed to remain intact until the tablet reaches the stomach, dissolution of the tablet would be delayed until the tablet reached the stomach and the coating had been breached – this process is inconsistent with a fast dissolve dosage form. As the Examiner notes (citing Mauger col 2, lines 39-63) on page 9 line 19, the coating of Mauger "melts". Melting means undergoing or causing to undergo the transition from solid to liquid [e.g. a phase change], while dissolving is to cause a substance to pass into solution. See Dorlands Medical Dictionary on line at www.mercksource.com. Thus, the attribute of the coating of Mauger is to undergo a physical phase change in the warmth of the body as opposed to dissolving.

Herein Applicants' have amended claim 1 to specifically claim a saccharide as an element of the fast dissolving granulation. Mauger provides no teaching, suggestion, or motiviation to use a saccharide even in the coating disclosed in Mauger much less any other capacity. Further, Mauger provides no teaching disclosure or motivation to use a fast dissolving granulation in a tablet in any capacity coating or otherwise. Accordingly, Mauger does not disclose, suggest or provide motivation for combining saccharide with a low melting point solid form to a fast dissolving granulation, and no teaching, suggestion or motivation for forming a tablet wherein about 30% to about 75% of the weight of the tablet is a fast dissolving granulation of a saccharide and a low melting point solid as Applicants' currently amended claim 1 requires.

As claims 5, 8, 9, 10 and 12 variously depend from claim 1, the present amendment to claim 1 replacing the term "low melting point compound" with "saccharide" and adding the limitation "and wherein the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet", applies to claims 5, 8, 9, 10 and 12, the amendment also further distinguishes claims 5, 8, 9, 10 and 12 from Wehling and Mauger for the reasons discussed above.

Thus Mauger neither teaches or suggests the elements needed to cure the identified deficiency of Mizumoto - namely Mauger does not teach or suggest that a saccharide and a low melting point compound are required; and/or or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation and/or that the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet.

There is no teaching or suggestion in Mizumoto, Mauger or in the combination of Mizumoto and Mauger of Applicants' invention of a combination of a saccharide and low melting point compound to form a fast dissolving granulation for use in a fast dissolve tablet. Accordingly, there is no teaching or suggestion that the fast dissolving granulation should be used in an amount of about 30% to about 75% of the weight of the tablet to from a fast dissolving tablet.

In view of at least these distinctions and the fact that Applicants have amended independent Claim 1 to replace " water soluble excipient" with at least one saccharide and specify that the fast dissolving granulation "comprises about 30% to about 75% of the weight of the tablet", Applicants respectfully request that the Examiner withdraw the rejection of independent claim1 and claims 5, 8-10, and 12 which variously depend form claim 1 under 35 USC §103 over Mizimuto. (US 5,178,878) in view of Mauger et al. (US 5,728,403).

Rejection Under 35 USC §103 – Makino

Claims 1-9 and 14 stand rejected under 35 USC §103 (a) over Makino (U.S. 5,501,861, herein "Makino"). The rejection is rendered moot as to claims 2-4, 6, 7, and 14 which have been cancelled with the current amendment.

Makino discloses a pharmaceutical preparation designed for buccal dissolution (see col. 2, lines 54-65) which is a compression molding of a carbohydrate, active agent, and a small amount of water that yields a "porous tablet ...capable of disintegration and dissolving rapidly in the oral cavity". As Makino discloses in column 5, lines 1-50 and column 6 lines 12-19, the key factors in creating the desired properties of the composition of Makino are the particle size of the carbohydrate, the proportion of carbohydrate to active, and the amount of water. The presence of the enough water to barely coat the surface of the particles appears to be a critical to obtaining the desired properties of the Makino composition. See column 6 lines 12 -31.

In contract to Applicants' invention, Makino neither teaches or suggests a fast dissolving granulation and/or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation and/or that the fast dissolving granulation comprises about 30% to about 75% of the weight of the fast dissolve tablet.

The Examiner states on page 11, first paragraph of the office action of October 12, 2007, that differences in amounts and/or ranges will not support patentability unless there is evidence indicating that the concentration is critical. One exemplary piece of evidence that shows Applicants' invention to be patentably distinct from Makino, is provided by comparing the hardness of the resulting tablets. Applicants claim a tablet of a hardness of less than about 2 kP. Applicants' claim is supported, for example, in Example 8 which recites that for compositions 1 and 2 of Example 8, the hardness ranges were 0.45 – 1.4 kP and 0.7 – 1.7 kP, respectively. Makino claims a tablet having a hardness of "3 to 20 kg". See Makino claim 1. Makino's examples show hardness values of 8-19 kg. See Tables 22-1, 22-2, 22-3 and 23. Thus, the hardness data indicates that Applicants' use of a fast dissolving granulation formed from a saccharide and a low melting point compound and the use of said fast dissolving granulation in an amount of about 30% to about 75% of the weight of the fast dissolve tablet yields a tablet with substantially different physical properties of Makino's tablet. One skilled in the art recognizes that tablet hardness may impact a number of properties of a tablet including for example, processability, robustness and dissolution behavior. As the data presented in Example 8 shows, Applicants' composition is tabletable to form a tablet with substantially lower hardness that that of Makino's. Namely, in contrast to Makino who claimed tablet hardness is in the range of 3-20 kg and whose data shows hardness values in the range of 8-10 kg. Applicants' composition forms a satisfactory tablet with a hardness less than 2 kP.

In view of at least these distinctions and the fact that Applicants have amended independent Claim 1 to further specify a saccharide and that the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet", Applicants respectfully request that the Examiner withdraw the rejection of independent claims 1 and dependent claims 5, 8 and 9 which variously depend from claim 1 under 35 USC §103 (a) over Makino.

Comments Regarding Examiner's Response to Applicants' Arguments in Response of 2/26/07

Applicants thank the Examiner for considering Applicant's Arguments and amendments filed 7/26/07 and withdrawing the rejections of claim 1 under 35 U.S.C. 112 2nd paragraph, claims 1-5, 7-10 and 13 under 35 U.S.C. 102(b) over Wehling, and claims 1-14 under 35 U.S.C. 103(a) over Korab in view of Mauger.

Applicant's have reviewed and considered the Examiner's response to their amendments and arguments filed 7/26/07. Applicants believe that the current amendments and the detailed comments provided herein above address the issues set forth in the Examiner's responsive comments regarding the rejection of claims under 35 U.S.C. § 102 over Mizumoto, under 35 U.S.C. § 102 over Shimuzu, under 35 U.S.C. § 103(a) over Wehling in view of Mauger, under 35 U.S.C. § 103(a) over Mizumoto in view of Mauger, and under 35 U.S.C. § 103(a) over Makino.

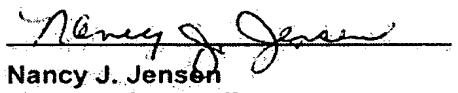
Further in response to the Examiners response to Applicant's arguments in Applicant's filing of 7/26/07, Applicants' are adding claims 34-37 in this response New claims 34-37 employ "consisting essentially of" language which Applicants' believe further points out and distinguishes Applicants' invention.

CONCLUSION

In view of the amended claim set presented herein and the above remarks, Applicants respectfully request that amended claim 1 and claims 5, 8, 9, 10, and 12 which depend from claim1 be allowed and that new claims 32-37 be entered and allowed.

Should the Examiner believe that anything further is desired in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's representative at 804-257-2544.

Respectively submitted,



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